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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,773	10/07/2003	Hajime Matsuzaki	3522.2	7374

22886 7590 10/16/2006

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,773	MATSUZAKI ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-4are pending in the instant application. All the arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The arguments at page 6 of the response are persuasive. Accordingly, the rejection under 35 USC 101 is withdrawn.

Claim Rejections - 35 USC § 112

3. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an array comprising a plurality of nucleic acid probes wherein the array comprises each of the sequences listed in SEQ ID NOS 1-124,031. The claims are further drawn to an array comprising the complements of each SEQ ID NO:, as well as probes in which one of the sequences listed in SEQ ID NOS 1-124,031 has a mismatch at the central position.

The specification teaches that the sequences of SEQ ID NOS 1-124,031 correspond to regions of the human genome containing SNPs (single nucleotide polymorphisms) (page 22). The specification teaches that for each of SEQ ID NO: 1-124,031, the "disclosure" includes probes with a mismatch anywhere in the nucleic acid sequence and may comprise one or more bases (page 21, lines 6-15). The claims recite probes "consisting essentially of" one of the sequences of SEQ ID NOS 1-1124,031. As the specification does not define the metes and bounds of "consisting essentially of", the recitation is considered "open" ie: comprising, as the specification does not define what is "essential" to the claimed nucleic acids along with the recited SEQ ID NOs. Therefore, the claims also again, encompass SNPS in sequences that have not been taught or described by the specification.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of nucleic acids consisting of SEQ ID NOS: 1-124,031, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co.

Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Response to Arguments

4. The response does not specifically address this rejection. At page 4, the response asserts that the "claimed probes" do not include any unspecified variations in the sequences provided" and at page 5, asserts that "applicants have used the 'consisting essentially of' language to indicate that the probes may be attached to the array via a linker molecule or sequence". These arguments have been thoroughly reviewed but were not found persuasive as the specification does not define the limits of a nucleic acid probe using this term nor does it exclude other sequences on either side of the recited SEQ ID NOS:.

Claim Rejections - 35 USC § 103

5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over dbSNP build 115 (June 1, 2003) or build 103 (April 8, 2002), each in view of Venter (US Patent 6,812,339).

The claims are drawn to arrays comprising probes which comprise one of SEQ ID NOS 1-124,031, wherein the probes of the array comprises each of SEQ ID NOS 1-124,031. Accordingly, the array comprises at least 124,031 probes, each probe comprising one of SEQ ID NOS 1-124,031. Claim 2 is further drawn to the array comprising the complement of each of the sequences of claim 1. Claim 2 is further drawn to a third set of probes comprising each of SEQ ID NOS 1-124,031, except with a mismatch at the central position.

DbSNP teaches single nucleotides polymorphisms in the human genome as well as at least 30 nucleotides on the 5' end and 30 nucleotides on the 3' end of the SNP. Absent evidence to the contrary, each build listed above, is taken to provide the SNP data in each of the sequences of SEQ ID NOS 1-124,031. dbSNP does not teach providing probes comprising these SNPs on an array. However, Venter teaches that there is a need to provide arrays with allele specific probes to detect SNPs in the human genome (see abstract, col. 15 line 1- col. 16, line 14). Venter teaches that preferably, the probes should hybridize to at least about a 12, 20, 25, 40 nucleotide region (col. 14, lines 55-65), are 10, 15, 20, 25, 30, 40 etc nucleotides long (para bridging cols. 17-18), are specific to each of the variants of the allele should be included allowing for the simultaneous analysis of each possible variant on the same support (col. 15, lines 25-35), and that the preferably, the polymorphic site aligns at the central position (col. 15, lines 21-25), or 5, 4, 3, 2, or 1 nucleotides form the center of the polynucleotide (col. 18, lines 3-7). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention

was made to have constructed an array of probes of 25 nucleotides, containing the SNP and corresponding allelic variants of each of the SNPs in dbSNP, because Venter teaches to provide SNP probes on an array for the purpose of detecting the variants in a sample. The ordinary artisan would have been motivated to provide array of probes containing the SNPs and alternate alleles taught in dbSNP because Venter teaches that such can be used to identify genes involved in complex disorders and enhance the selection of candidate genes most likely to contain causative SNPs associated with a particular disease. Although Venter does not teach to provide the complement of each probe, it would have been further prima facie obvious to one of ordinary skill in the art to also provide the complement of each SNP probe to identify the appropriate SNP on either DNA strand (sense or antisense).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over dbSNP Build 103 of 115, each in view of Venter as applied to claims 1-3 above, and further in view of Lough et al (US Patent 5,900,481).

The teachings of the dbSNP database in view of Venter is set forth above. The dbSNP database in view of Venter does not teach an array comprising probes specifically attached to a bead, however Lough teaches that as compared to flat surfaces, the immobilization of nucleic acids on a bead which are linked to a solid support provides for increased surface area. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use beads for immobilization of nucleic acids as taught by Lough, on the array of dbSNP database in view of Venter because Lough teaches that as compared to flat

surfaces, the immobilization of nucleic acids on a bead which are linked to a solid support provides for increased surface area.

Response to Arguments

7. The response traverses the rejections under 35 USC 103 and asserts that the claims are drawn to a specific set of probes to genotype a specific set of probes to a specific set of more than 10,000 human SNPs that have been carefully selected from the mote than 5 million common SNPs, and that Venter or dbSNP do not teach this specific set of probes or the specific set of SNPs targeted by these probes. This argument has been thoroughly reviewed but was not found persuasive. The claims are drawn to "an array comprising a plurality of nucleic acid probes" and are thus not limited to a specific set of probes. It is acknowledged that none of the cited references provide motivation to arrive at an array consisting of the 124,031 probes wherein each probe consists of each of one of the specifically recited SEQ ID NOS: 1-124,031. However, the claims are more broadly drawn to an array which can contain additional probes (comprising), as well as where each probe is not limited to the specifically recited sequences but can have sequences on either side given the transitional phrase "consisting essentially of" and are not limited to the specific set of probes or SEQ ID NOS as recited in the claims.

Conclusion

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Jehanne Sitton
Primary Examiner
Art Unit 1634

10/5/06